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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,012	05/29/2001	Chaitan Khosla	300622000212	9415
25225	7590	02/11/2004	EXAMINER	
MORRISON & FOERSTER LLP 3811 VALLEY CENTRE DRIVE SUITE 500 SAN DIEGO, CA 92130-2332			KERR, KATHLEEN M	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/870,012	<b>Applicant(s)</b> KHOSLA ET AL.	
	<b>Examiner</b> Kathleen M Kerr	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 18, 19 and 24 is/are pending in the application.  
     4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/30/03 12/15/03</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action, a non-Final rejection (mailed on July 1, 2003), Applicants filed an amendment and response received on December 15, 2003. Said amendment amended Claims 19 and 24 and cancelled Claims 20, 21, and 23. Thus, Claims 18-19 and 24 are pending in the instant Office action.

Claim 18 remains withdrawn from consideration as a non-elected invention (election by Applicants without traverse in Paper No. 7). Claims 19 and 24 will be examined herein.

### ***Priority***

2. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/003,338 filed on July 6, 1995 and the U.S. non-Provisional Application No. 08/675,817 (now USPN 6,080,555) filed on July 5, 1996. Neither of these applications, however, disclosed the claimed invention of Claims 19-24.

The instant application is granted the benefit of priority for the U.S. non-Provisional Application No. 08/896,323 (USPN 6,066,721) filed on July 17, 1997 and the U.S. non-Provisional Application No. 08/434,289 (now USPN 6,261,816) filed on November 5, 1999. These applications do disclose the claimed invention. Thus, the earliest effective filing date of the claimed invention is considered to be July 17, 1997.

***Withdrawn - Claim Rejections - 35 U.S.C. § 112***

3. Previous rejection of Claims 19-21 and 23-24 under 35 U.S.C. § 112, second paragraph, as being indefinite for the terms “macrolide” and “antibiotic” is withdrawn by virtue of Applicants’ amendment deleting these terms in Claims 19 and 24.

4. Previous rejection of Claims 19-21 and 23-24 under 35 U.S.C. § 112, second paragraph, as being indefinite for how the adjectives in “heterologously and recombinantly produced macrolactone polyketide” help define the macrolactone compound added to the culture is withdrawn by virtue of Applicants’ amendment removing these terms.

5. Previous rejection of Claims 19-21 and 23-24 under 35 U.S.C. § 112, first paragraph, new matter, is withdrawn by virtue of Applicants’ amendments to the claims.

6. Previous rejection of Claims 20, 23, and 24 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants’ cancellation and/or amendment of said claims.

7. Previous rejection of Claim 21 under 35 U.S.C. § 112, first paragraph, enabling deposit, is withdrawn by virtue of Applicants’ cancellation of said claim.

***Withdrawn - Claim Rejections - 35 U.S.C. § 102***

8. Previous rejection of Claims 19 and 20 under 35 U.S.C. § 102(e) as being anticipated by Katz *et al.* (USPN 5,824,513) is withdrawn by virtue of Applicants’ amendments. While the

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metes and bounds of the terms 6dEB and erythromycin derivatives are unclear, an ordinarily skilled artisan would not extend this definition to a butyl thioester of a  $\delta$ -lactone.

## **NEW ISSUES**

### ***Claim Objections***

9. Claim 19 is objected to for misspelling the second occurrence of "erythraea"; the correct spelling is ---crythraea--- as elsewhere in the claim. Correction is required.

### ***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 19 and 24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claims 19 and 24, the term "erythromycin derivative" and in Claim 19 alone, the term "6-dEB derivative" are confusing as to their metes and bounds. In the art, 6-dEB can be considered an erythromycin derivative and vice versa. The specification does not clearly define the metes and bounds of the terms. In Figure 3, Compounds 1, 6, and 7 are named as 6-dEB derivatives; and Compounds 9-11 are named as erythromycin derivatives; however, the terms have much broader meanings in the art, which result in the confusion. Applicants' remarks of record concerning the amendment describe 6dEB derivatives being unglycosylated while the erythromycin derivatives are glycosylated, but such a limitation cannot be read into the claims. Thus, the metes and bounds of the terms are unclear. Clarification is required.

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11. Claims 19 and 24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The abbreviation "6-dEB" is used in the claims without definition upon its first occurrence. The Examiner suggests ---6-deoxyerythronolide B (6-dEB)--  
- for clarity. Clarification is required.

12. Claims 19 and 24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear if the phrase "6-dEB derivative produced in a recombinant organism other than *Saccharopolyspora erythraea*" is a real method step meant to limit the claim or is merely some means of limiting the 6-dEB derivative. If the latter is intended, it is unclear how this phrase actually limits the term's scope. Clarification on these points is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 19 and 24 are rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

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in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As previously noted, the instant claims gather their support only from Example 4 as originally filed. In Example 4, mutant A34 is fed 6-dEB and makes an unnamed antibiotic, and mutant A34 is fed compounds 6 and 7 and produces compounds 10 and 11, respectively, as evidenced after extraction. There is no support in Example 4 for the following concepts found in the claims:

- a) using *any* 6-dEB derivative in the “adding” step, provided that the term “6-dEB derivative” has a scope broader than defined in Figure 3 (that is compounds 1, 6, and 7),
- b) making *any* erythromycin derivative in the “culturing” step, provided that the term “erythromycin derivative” has a scope broader than defined in Figure 3 (that is compounds 9, 10 and 11), and
- c) the phrase “6-dEB derivative produced in a recombinant organism other than *Saccharopolyspora erythrae*” since the additive in Example 4 comes from an *S. erythraea* mutant, A34.

#### ***Additional Art of Record***

14. Upon review of the search of the newly amended claims, the Examiner cites the following art as related, but not prior art and thus not anticipatory:

- a) Liu *et al.* Biosynthesis of 2-Nor-6-deoxyerythronolide B by Rationally Designed Domain Substitution. J. Am. Chem. Soc. (October, 1997) 199:10553-10554. Liu *et al.* teaches feeding *S. erythraea* compound 2 (a 6dEB derivative, see Figure 1) to produce 2-norerythromycin (see page 10553, right column).

*Summary of Pending Issues*

15. The following is a summary of the issues pending in the instant application:
- a) Claim 19 stands objected to for misspelling the second occurrence of “erythrae”.
  - b) Claims 19 and 24 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “erythromycin derivative” and the term “6-dEB derivative”
  - c) Claims 19 and 24 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the abbreviation “6-dEB”.
  - d) Claims 19 and 24 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the unclear phrase “6-dEB derivative produced in a recombinant organism other than *Saccharopolyspora erythraea*”.
  - e) Claims 19 and 24 stand rejected under 35 U.S.C. § 112, first paragraph, new matter.

*Conclusion*

16. No claims are allowed for the reasons identified in the numbered sections of this Office action for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO




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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
NASHAAT T. NASHED PHD.  
PRIMARY EXAMINER



Kathleen M Kerr  
Examiner  
Art Unit 1652

February 4, 2004